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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,146	10/31/2006	Ulrich Kaiser	20831/0204871-US0	4136
7278	7590	12/01/2009	EXAMINER	
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			ALEXANDER, LYLE	
			ART UNIT	PAPER NUMBER
			1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,146	Applicant(s) KAISER, ULRICH	
	Examiner LYLE A. ALEXANDER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/28/05</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite as to what structure is intended. The claim indicates “a detector volume designed to house an indicator connected to a gas sterilization chamber ...”. The claim fails to positively recited the detector has a closed volume and houses an indicator that is connected by a connector to a sterilization chamber. The claim also fails to clearly describe the connector has a tapering reduction of cross sectional area. For the purposes of examination this claim will be interpreted as a closed volume detector containing an indicator connected to a sterilization chamber by a connector that has a cross section narrowing in the direction of the detector chamber.

Claim 3 claims the volume as “mm²” which is confusing because volume of a chamber would be represented as “mm³”. For the purposes of examination “mm³” will be assumed.

Claim 4 is not clear if the channel is connected to the detector or sterilization chamber. Additionally, it is not clear what is the purpose of the channel. Finally in the last line “better ca.” appears to be a typographical error.

Claims 5-8 are not clear what structures are intended by "stages".

Claim 9 is not clear what is the minimum collector volume. As presently claimed it could be zero.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 97/12637.

5. WO 97/12637 teach a sterilant challenge device to test the efficiency of air removal during a sterilization cycle. Tube(2) connect receives the sterilant and is used to determine the amount of air and non-condensable with the bore. Figures 1-3 show the device(1) is generally cylindrical comprising a tube(2) with a bore(3) that has open end(5) that is exposed to the sterilization environment and a closed end(4) that is in contact with a sensor(7). Detection of sterilant by sensor(7) indicated that a sterilization cycle has been effective. Page 9 lines 25+ teach the tube(2) has a bore length of less than 30cm, preferably less than 20cm and most preferably less than 10cm and 7.5 cm. Page 10 lines 14-22 teaches the outer diameter of tube(2) is less than 5cm and the inner diameter of the bore(3) is less than 0.9cm and preferably 0.6cm. Page 14 lines 12-15 describe figure 3 as teaching the cross section of the bore(3) is decreasing towards the sensor(7). Page 15 lines 25+ teach that either a chemical or biological

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indicator can be used as the sensor(7). Page 17 lines 5+ teaches in figure 6 the compartments could be arranged "one inside another" and each compartment is individually "thermially-insulated".

6. The claimed "*test device*" has been read on the taught **device(1)**, the claimed "*indicator connected to a sterilization chamber*" has been read on the taught **sensor(7)**, the claimed "*gas-collection-volume being multi-stage-designed*" has been read on the taught figure 3 where the **bore(3) is decreasing towards the sensor(7)**.

7. With respect to claim 2 the claimed decreases towards the detector of between 50% and 75% have been read on figure 3.

8. With respect to claims 3-4, the taught lengths are indistinguishable and would inherently have the same volume.

9. With respect to claims 5-8, they have been read on page 17 lines 5+ that teaches in figure 6 the compartments could be arranged "one inside another" and each compartment is individually "thermally-insulated".

10. Claim 9 requires the detector volume to be less than 500ul. WO 97/12637 does not explicitly teach what the volume is of sensor(7). However, WO 97/12637 teaches the preferred diameter of the tube(3) is less than 0.9cm and preferably 0.6cm. From figure 2 it is evident the sensor has a smaller diameter than the tube(3) and the sensor(7) would have a diameter of less than 0.6cm (e.g. a diameter less than the tube(3)). The Office has measured the relative lengths of figure 2 and concluded the bore(3) has an illustrate length of 2.75" and the sensor(7) an illustrated length of 0.5" making the ratio of the length of the sensor(7) to the bore(3) "0.18". Uses the taught

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bore(3) length of less than 10 cm, then the sensor(7) would have a length of less than 1.8 cm. The volume of the sensor bases upon a bore(3) diameter of less than 0.6cm and a length of less than 1.8cm would yield a volume indistinguishable from the claimed volume of less than 500 microliters.

11. With respect to claim 10, it has been read on page 15 lines 25+ that teaches 3 either a chemical or biological indicator can be used as the sensor(7).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/LYLE A ALEXANDER/
Primary Examiner, Art Unit 1797
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